

(B) a structural nucleic acid molecule, wherein said structural nucleic acid molecule encodes a protein or fragment thereof selected from the group consisting of a *Glycine max* protein or fragment thereof in Table 1; which is linked to

(C) a 3' non-translated sequence that functions in said cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

5. (Once Amended) A transformed plant comprising a cell according to claim 3, wherein said plant is a dicot.

6. (Once Amended) A transformed plant comprising a cell according to claim 3, wherein said plant is a monocot.

REMARKS

Claims 1 and 2 have been cancelled, and claims 3-11 will be pending following the entry of this amendment. Claims 3, 5 and 6 have been amended. Support for these amendments may be found throughout the application, including the originally filed claims and sequence listing. No new matter is introduced by these amendments. The specification has been amended in accordance with MPEP 608.01 so that no browser executable code is presented.

Applicants do not believe that any fees other than those required for a two (2) month extension of time are required in conjunction with this response. However, if any additional fees are required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Arnold & Porter Deposit Account No. 50-1824 referencing matter number 16517.132.

I. Information Disclosure Statement.

Applicants note for the Examiner's attention that an information disclosure statement (IDS), a PTO form 1449, and twenty six accompanying references were submitted in the instant

application on 24 August, 2001. Applicants respectfully request the Examiner to return a signed copy of the 1449 indicating the references had been considered during prosecution with the next response.

II. Restriction Requirement

The Examiner required restriction to one of the following three groups under 35 U.S.C.

121.

I. Claims 1-3, 5-7 and 9-10, drawn to nucleic acids, host cells, and transgenic plants wherein the expression constructs comprise the nucleic acid in the sense orientation, classified in class 536, subclass 23.1, for example.

II. Claims 1-10, drawn to nucleic acids, host cells, and transgenic plants wherein the expression constructs comprise the nucleic acid in the anti-sense orientation, classified in class 536, subclass 24.5, for example.

III. Claim 11, drawn to a method for determining a genomic polymorphism in a plant that is predictive of a trait, classified in class 425, subclass 6.

The Examiner further required restriction to a single nucleic acid sequence for prosecution on the merits.

Applicants acknowledge the election of Group I, SEQ ID NO: 1, with traverse, for prosecution on the merits.

Applicants submit that the Patent Office has not proven that an undue burden would be imposed by the search and examination of the entire application, and that the complete examination would be handled most expeditiously by treating all of the pending claims as a single entity. As MPEP 803 directs, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it

includes claims to independent or distinct inventions.” Applicants submit the Examiner has not only failed to prove an undue burden exists in the examination of the entire application, but further, that the Examiner has failed to even address why an undue burden would exist in the examination of all claims as directed to a single nucleotide sequence. No serious burden is created for the Examiner by running a simultaneous computerized search of a single nucleic acid sequence in both orientations. A single search may be run in conjunction with databases such as those available at <http://www.ncbi.nlm.nih>, that would automatically yield results from Groups I and II without any undue burden on the Examiner. In addition, Applicants submit that the same search would search would also provide results required for Group III.

Based upon the foregoing, Applicants submit that the restriction requirement is improper and therefore must be withdrawn.

III. Claim Objections

Applicants note the objection to claims 1-3, 5-7, 9 and 10. Applicants respectfully request that the Examiner’s objection, which is based upon the asserted failure to limited the claims to SEQ ID NO: 1, be held in abeyance until the restriction requirement is made final.

IV. Sequence Rules

Applicants have amended the sequence listing to incorporate those sequences set forth on pages 96-97 of the disclosure. No new matter is added by the amendments. A copy of the sequence listing in computer readable form (CFR) and 2 copies of the sequence listing on compact disc accompany this response. In view of the foregoing, Applicants submit the application complies with the sequence rules.

V. Specification

The Examiner has objected to the disclosure at pages 1, 4, 5, 7, 24 and 96 as allegedly containing embedded hyperlinks and/or other forms of browser executable code. Applicants have amended the specification on pages 1, 4, 5, 24 and 96 such that the text no longer contains browser executable code. Applicants respectfully submit that the sites recited on page 7 are neither active hyperlinks, nor code which is immediately browser executable, and therefore comply with MPEP 608.01. Applicants submit that the amendments to the specification render the objections moot, and request the Examiner to withdraw the objection.

VI. Rejection of Claim 2 under 35 U.S.C. §101/112

Claims 1-3,5-7, 9 and 10 are rejected under 35 U.S.C. §101/112 first paragraph, because the claimed invention is allegedly not supported by a specific, substantial and credible utility or by a well-established utility.

The Examiner asserts that the use of the disclosed nucleic acids in genetic mapping, expression monitoring, homology studies, site directed mutagenesis, transformation, and cosuppression are general, and are not specific to the sequences claimed. The Examiner also asserts that no specific function has been assigned to the polypeptide encoded by SEQ ID NO: 1, and no utility has been described for the transgenic plants comprising these nucleic acids.

Applicants respectfully disagree with the Examiner. One of the utilities is the use of the claimed nucleic acid molecule is genetic mapping. Specification at page 42, line 19, through page 49, line 8. Another one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 49, line 3 through page 57, line 9. The Examiner argues that these utility, like all of the asserted utilities, is not specific or substantial, but does not provide any support (legal or factual)

for the proposition that these utilities are not a legal utilities. Many of the disclosed utilities in this case, including these utilities, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The fact that, for example, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-25.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms or in genetic mapping is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

In view of the foregoing, Applicants submit that the Examiner's assertions are misplaced, and that Applicants have met their burden under 35 U.S.C. 101. The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism or for genetic mapping. These benefits are immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public

satisfies the utility requirement of 35 U.S.C. § 101 in the form of a specific, substantial and credible utility.

The Examiner has not provided any evidence that would reasonably suggest that the claimed nucleic acids cannot be used for the aforementioned utilities, and therefore has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d at 1567, 34 U.S.P.Q.2d at 1441. The Examiner "must do more than merely question operability - [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules, which in their current form, provide specific benefits to the public, for example the ability to identify the presence or absence of a polymorphism in a population of plants, or as tools for genetic mapping. These benefits are specific, not vague or unknown, and provide "real world" or substantial benefits.

Further more, they are as applicable to the nucleic acids claimed as to the plants transformed with them. Because the claimed nucleic acids and plants provide a benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids and plants for the disclosed utilities, the additional requirements of 35 U.S.C. § 112 have been met.

For at least the foregoing reasons, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities. Consequently, the rejection under 35 U.S.C. §101 is incorrect and should be withdrawn. Applicants further submit that the accompanying rejection under 35 U.S.C. 112 first paragraph should also be withdrawn.

VII. Rejection of Claims 1-2 and 10-22 under 35 U.S.C. §112, 1st Paragraph: Written

Description

Claims 1-5, 7 and 27 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing.

Applicants respectfully submit that the cancellation of claims 1 and 2 renders the instant rejection moot with regard to these claims. Moreover, Applicants respectfully note that claim 4 stands withdrawn from examination pursuant to the restriction requirement issued by the Examiner, and there is no claim 27 pending in the instant application¹.

According to the Examiner, the specification provides insufficient written description to support the invention claimed. Applicants respectfully disagree and contend that they were in possession of SEQ ID NO 1 at the time of invention. Moreover, the disclosure provides a

¹ Applicants note that claims 9 and 10 have not been included in the instant rejection.

detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. In view of the foregoing, Applicants maintain that they have met their burden under 35 U.S.C. 112 first paragraph as set forth by our reviewing courts in *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, because the disclosure "clearly allow[s] persons of ordinary skill in the art to recognize that [Applicants] invented what is claimed." Moreover, by presenting SEQ ID NO: 1, Applicants have provided a detailed chemical structure of the claimed nucleic acids and thereby meet the burden set forth in *Fiers v. Revel* 984 F.2d 1164, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993).

In addition to the arguments discussed above, the Examiner asserts that Applicants have not provided guidance or description as to how to select fragments from SEQ ID NO: 1 which will retain the function of SEQ ID NO: 1. Applicants note that there is no basis for such an assertion in either the Examiner's cited case law or in the statute. Applicants respectfully request the Examiner to reconsider and withdraw this argument.

In view of the foregoing, Applicants respectfully request that the written description rejection under 35 U.S.C. §112, 1st paragraph be withdrawn.

VIII. Rejection under 35 U.S.C. §112 second paragraph

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 112 second paragraph as allegedly being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants submit that the cancellation of claims 1 and 2 renders the rejection moot regarding these claims. In addition, claim 3 has been amended to provide antecedent basis for the clause "the transformed plant according to claim 3" that is recited in dependent claims 5 and 6. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under § 112 second paragraph.

IX. Non-statutory Double Patenting

Claims 1-3 are provisionally rejected under the judicially created doctrine of obvious type double patenting as being obvious over claims 1-9 and 16 of copending application 09/421,106; and, claims 1-3, 5-7 and 9-10 are provisionally rejected under the judicially created doctrine of obvious type double patenting as being obvious over claims 1-9 and 16 of copending application 09/521,640.

Applicants note the provisional nonstatutory double patenting rejections. As the rejection is provisional, Applicants are under no immediate obligation to respond to the rejection. Applicants respectfully request that the rejection be held in abeyance until allowable subject matter is identified.

X. Rejection under 35 U.S.C. §102

Claims 1-3 are rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Marek, *et al.* (GenBank Accession AQ989165, March, 2000).

The rejection of claims 1 and 2 is rendered moot by their cancellation. Applicants respectfully disagree with the rejection of claim 3 as being anticipated by the Marek reference. In order to sustain a rejection under 35 U.S.C. 102(a) over the Marek reference the Examiner must establish that the subject matter of the instant claims described in a printed publication in this or a foreign country, before the invention thereof by applicant. Applicants submit the date set forth on the GenBank printout does not establish the date of public availability. Further to the foregoing, Applicants note the current application claims priority under 35 U.S.C. 120 to U.S. patent applications 09/521,640, filed, March 10, 2000 and 09/421,106, filed October 15, 1999.

In view of the foregoing, applicants submit that the rejection under 35 U.S.C. 102(a) should be withdrawn.

Claims 1-3 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Wing *et al.* (GenBank Accession AQ256798, October 1998).

The rejection of claims 1 and 2 is rendered moot by their cancellation. Applicants submit that they are entitled to priority under 35 U.S.C. 120 to U.S. patent applications 09/521,640, filed, March 10, 2000 and 09/421,106, filed October 15, 1999. As such, claim 3 has an effective filing date less than one year prior to the October 23, 1998 date relied on by the Examiner. In view of the foregoing, Applicants submit that the rejection under 35 U.S.C. 102(b) is incorrect and should be withdrawn.

Claims 1-3, 5-7 and 9-10 are provisionally rejected under 35 U.S.C. 102(e) as allegedly being anticipated by copending applications 09/421,160 and 09/521,106. Applicants noted the provisional rejections over copending applications 09/521,640 and 09/421,106 and respectfully request that these provisional rejections be held in abeyance until otherwise allowable subject matter is identified.

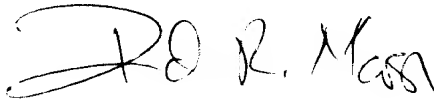
Claims 1-3, 5-7, 9 and 10 are rejected under 35 U.S.C. 102(f) because Applicants allegedly did not invent the subject matter. In view of Applicants election in response to the restriction requirement under 35 U.S.C. 121, Applicants request the Examiner to reconsider and withdraw the rejection.

SUMMARY

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for

any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "D R. Marsh". The signature is fluid and cursive, with the first name "D" being a large, stylized letter.

David R. Marsh (Reg. No. 41,408)

June E. Cohan (Reg. No. 43,741)

Date: February 19, 2002

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MARKED UP VERSION OF THE AMENDMENTS PURSUANT TO 37 C.F.R. 121

In the Specification

Page 1, line 17 through page 2 line 2.

Sequence tagged connectors, or STCs, are sequences of insert data generated from both ends (at the vector-insert point) of a BAC clone in a genomic library. These sequences, and BACs containing these STC sequences, can be used, for example, for marker development, genetic mapping or linkage analysis, marker assisted breeding, and physical genome mapping (Venter, *et al.*, *Nature*, 381:364-366 (1996), the entirety of which is herein incorporated by reference; Choi and Wing, [[http://www.](http://www.genome.clemson.edu/protocols2-nj.html)] available on the world wide web at: [genome.clemson.edu/protocols2-nj.html](http://www.genome.clemson.edu/protocols2-nj.html) July, 1998). STCs can represent a copy of up to a full length of a mRNA transcript, a promoter element or part of a promoter, can contain simple sequence repeats (also called microsatellites) repetitive elements or fragments of repetitive elements, other DNA markers, or any combination thereof.

Page 4, line 20 to page 5, line 7.

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ), accessible on the world wide web at [[\(http://www.ddbj.nig.ac.jp/\)](http://www.ddbj.nig.ac.jp/)]; Genebank, accessible on the world wide web at [<http://www.ncbi.nlm.nih.gov/web/Genbank/Index.html>]; and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL), accessible on the world wide web at [http://www.ebi.ac.uk/ebi_docs/embl_db.html]. A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequences queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries

(BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology*, 12:76-80 (1994); Birren, *et al.*, *Genome Analysis*, 1:543-559 (1997)).

Page 24, lines 8-14.

Genomic sequences can be screened for the presence of proteins or genes utilizing one or a number of different search algorithms have that been developed, one example of which are the suite of programs referred to as BLAST programs. Other examples of suitable programs that can be utilized are known in the art, several of which are described above in the Background and under the section titled "Uses of the Agents of the Invention." In addition, unidentified reading frames may be screened for protein coding regions by prediction software such as GenScan, which is located on the world wide web at [<http://gnomic.stanford.edu/GENSCANW.html>].

Page 96, lines 9 to page 97 line 8

Primers are designed from good quality unique sequences. A public available primer software program, PRIMER 3, (Cambridge, MA) is used. PRIMER 3 can be accessed through the internet at [<http://www.genome.wi.mit.edu/cgi-bin/primer/primer3.cgi>]. Default parameters are used except for those product size primer size changed. Product size is Min: 80, Opt: 100, Max 120, while Primer Size is Min: 18, Opt. 22 and Max 27. Oligos are synthesized by Genosis Biotechnologies, Inc. Houston, Texas).

The above protocols are used to develop primers from Sequence id

GM_M02_A2_B07_MR_MR containing the following nucleotide composition:

AGGCGTTTTNCCTTGATACCTTCGNAGGTCCANCCTTTNCTTGCTGTATCGACTCAT
TAACACCAAGCTCGGTGAGCACTCTGAAGATTATGACAACTTTCGNTGATCTTTTTG
TCATCGATATTNTAGNAGAGACCAATCTTCTTCTTCAAATGTCGCTCATGATATTTA
TTGTAATTATCTTCAATGTATGTCCAAAAAGTTAACCTTTTTTGGACCCCCACAATAG

AAATCTTTGAAATATTTAGCCATGTGTTGGCAAGCCATTCATATTTCTTTGCGGAGA
AACATGATCTATTGTGTCTTTTCGGATGCTTCTTCTATGTCTTCTTCTTCTTCTTCTT
CTTCTTCTTCTTCATTGACCACAATATTATCCAACCTCAACTTAGGTGCAAAATGGTGG
AATTTGAGACTTTGACGCANAGTCAGATGGTGCGTCATGCTCTTTCATTACATTGGA
CATCATNTACTACCCTTTGAAGACCCTCGATCCATGGAAGGGTTAATTGGTG, SEQ ID
NO: 20083.

This sequence contains CTT dinucleotide repeats with a repeat unit of 11. Using the Primer 3 program, two primers are selected: SER157F GTGTCTTTCGGATGCTTCTTCT (SEQ ID NO: 20084) and SER157R CACCATTTTGCACCTAAGTTGA (SEQ ID NO: 20085).

When these two primers are used to amplify genomic DNAs from eight different varieties, Minsoy, Noir, PIC, HS-1, A3244, H6686, A0868 and H5088, three alleles are detected. Sizes of these alleles ranged from 80 to 110 bp. The size variation in the PCR products result from repeat numbers in different varieties.

In the claims

3. (Once Amended) A transformed plant cell having a nucleic acid molecule which comprises:

(A) an exogenous promoter region which functions in said cell to cause the production of a mRNA molecule; which is linked to

(B) a structural nucleic acid molecule, wherein said structural nucleic acid molecule encodes a protein or fragment thereof selected from the group consisting of a *Glycine max* protein or fragment thereof in Table 1; which is linked to

(C) a 3' non-translated sequence that functions in said cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

5. (Once Amended) A [The] transformed plant comprising a cell according to claim 3,
wherein said plant is a dicot.

6. (Once Amended) A [The] transformed plant comprising a cell according to claim 3,
wherein said plant is a monocot.